



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/501,442

10/29/2005

Janne Kerovuo

D2000-1WUS

8134

29062 7590 03/25/2008

VERENIUM CORPORATION
Intellectual Property Department
P.O. Box 910550
SAN DIEGO, CA 92191-0550

EXAMINER

SWOPE, SHERIDAN

ART UNIT

PAPER NUMBER

1652

MAIL DATE

DELIVERY MODE

03/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/501,442	Applicant(s) KEROVUO ET AL.	
	Examiner SHERIDAN SWOPE	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1, 9, 16, 24, 27, 31, 34-36, 40, 43, 45, 49, 51, 52, 54, 55, 61, 68, 81, 86, 87, 91, 93-95, 97-99, 101, 103, 106, 107, 111, 121, 123, 126, 136, 137, 141, 145, 146, 151, 153, 158, 164-166, 169, 170, 173, 174, 177-179, 190, 191, 194-197, 199, 201, 203-205, 208, 209, 212, 214-216, 218-221, 223-226, 229 and 231-233 and 236-241 is/are pending in the application.

4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 9, 16, 24, 27, 31, 35, 36, 40, 49, 52, 94, 101, 165 and 238-240 is/are rejected.
- 7) ☒ Claim(s) 1, 9, 16, 24, 27, 31, 35, 36, 40, 49, 52, 94, 101, 165 and 238-240 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 July 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>0105;0306;0107;0407</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims withdrawn from consideration are

34,43,45,51,54,55,61,68,81,86,87,91,93,95,97-

99,103,106,107,111,121,123,126,136,137,141,145,146,151,153,158,164,166,169,170,173,174,177-179,190,191,194-197,199,201,203-205,208,209,212,214-216,218-221,223-226,229,231-233,236,237 and 241.

DETAILED ACTION

Applicant's election with traverse of Invention I, sub-invention (C) pectate lyase, and SEQ ID NO: 77/78, in their response of December 4, 2007 is acknowledged. The elected invention is directed to the polynucleotide of SEQ ID NO: 77, or variants thereof encoding a pectate lyase (EC 4.2.2.2), vectors and host cells comprising said polynucleotide, and methods of making the encoded protein.

Applicants' traversal is based on the following arguments.

(A) van der Hoeven et al, 2001, the prior art teaching a polynucleotide comprising 15 contiguous bases having 87% homology with SEQ ID NO: 1 and anticipating prior Claim 1, is no longer relevant as recitation of SEQ ID NO: 1 has been deleted from the claims.

(B) The polypeptide of SEQ ID NO: 132 consists of residues 359-680 of SEQ ID NO: 78, with an N-terminal methionine added. The polypeptide of SEQ ID NO: 134 is identical with SEQ ID NO: 132 with a single amino acid substitution; SEQ ID NO: 132 & 134 have 97.5% identity.

The arguments are not, or are, found to be persuasive for the following reasons.

(A) Reply: It is acknowledged that van der Hoeven et al is not relevant to the instant claim set. For the instant claim set, the technical feature linking the claims appears to be that they all relate to the polynucleotide of SEQ ID NO: 77, or variants thereof encoding a pectate lyase. Brown et al, 2001 (IDS) teaches a polynucleotide encoding a polypeptide having 72% identity with SEQ ID NO: 78, which anticipates Claim 1 herein; see the rejection under 35 USC 102. Therefore, the technical feature linking the current claims is not a special technical feature, as it is not a contribution over the prior art.

Art Unit: 1652

(B) Reply: Regarding SEQ ID NO: 131, this argument is found to be persuasive, as SEQ ID NO: 131 is encompassed by SEQ ID NO: 77 with addition of a codon encoding an N-terminal methionine, which is an obvious modification, and a substitution of the termination codon “taa” with “tag”, also an obvious substitution. Regarding SEQ ID NO: 133, this argument is found to not be persuasive. SEQ ID NO: 133 is not encompassed by SEQ ID NO: 77 and the mutational difference is not an obvious modification.

The restriction requirement is still deemed proper and is therefore made FINAL.

It is acknowledged that Claims 1, 9, 16, 24, 27, 55, 61, 68, 81, 95, 103, 141, 151, 158, 170, 173, 174, 177-179, 190, 191, 194-197, 199, 204, 205, 208, 209, 212, 214, 216, 218, 219, 224-226, and 231-233 have been amended, Claims 2-8, 10-15, 17-23, 25, 26, 28-30, 32, 33, 37-39, 41, 42, 44, 46-48, 50, 53, 56-60, 62-67, 69-80, 82-85, 88-90, 92, 96, 100, 102, 104, 105, 108-110, 112-120, 122, 124, 125, 127-135, 138-140, 142-144, 147-150, 152, 154-157, 159-163, 167, 168, 171, 172, 175, 176, 180-189, 192, 193, 198, 200, 202, 206, 207, 210, 211, 213, 217, 222, 227, 228, 230, 234, and 235 stand cancelled, and Claims 236-241 have been added. Claims 1, 9, 16, 24, 27, 31, 34-36, 40, 43, 45, 49, 51, 52, 54, 55, 61, 68, 81, 86, 87, 91, 93-95, 97-99, 101, 103, 106, 107, 111, 121, 123, 126, 136, 137, 141, 145, 146, 151, 153, 158, 164-166, 169, 170, 173, 174, 177-179, 190, 191, 194-197, 199, 201, 203-205, 208, 209, 212, 214-216, 218-221, 223-226, 229 and 231-233 and 236-241 are pending. Claims 34, 43, 45, 51, 54, 55, 61, 68, 81, 86, 87, 91, 93, 95, 97-99, 103, 106, 107, 111, 121, 123, 126, 136, 137, 141, 145, 146, 151, 153, 158, 164, 166, 169, 170, 173, 174, 177-179, 190, 191, 194-197, 199, 201, 203-205, 208, 209, 212, 214-216, 218-221, 223-226, 229 and 231-233 and 236, 237, and 241 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being

no allowable generic or linking claim. Claims 1, 9, 16, 24, 27, 31, 35, 36, 40, 49, 52, 94, 101, 165, and 238-240 are hereby examined.

Priority

The priority date granted for SEQ ID NO: 77 and 78 is April 4, 2003, the filing date of US 60/460,842, which discloses said sequences. The priority date granted for SEQ ID NO: 131 and 132 is April 2, 2004, the filing date of PCT/US04/10229, which discloses said sequences.

Drawings-Objections

Figure 8 is objected to because the Office's copy is illegible, the labeling across the top and sides is not explained, and the abbreviations and symbols are not explained.

Specification-Objections

The specification at page 153, paragraphs 3-6, is confusing. Lines 22-23 therein state that the polypeptide of SEQ ID NO: 134 was used for the formulation studies, while line 29 states that the polypeptide of SEQ ID NO: 78 was used. Clarification is needed.

Claims-Objections

Claim 1, 9, 16, 24, 27, 31, 35, 36, 40, 49, 52, 94, 101, 165, and 238-240 are objected to for reciting non-elected subject matter including the polynucleotide of SEQ ID NO: 133 and any polynucleotide encoding SEQ ID NO: 134 as well as enzymatic activities not encompassed by pectate lyase (EC 4.2.2.2) activity (see NiceZyme enclosure).

Claim Rejections - 35 USC § 112-Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1652

Claims 1, 9, 16, 24, 27, 31, 35, 36, 40, 49, 52, 94, 101, 165, and 238-240 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the following reasons.

For Claim 1, the phrase “encoding a polypeptide having... at least% sequence identity to SEQ ID NO: 77” renders the claim indefinite since SEQ ID NO: 77 is a polynucleotide. The skilled artisan would not know the metes and bounds of the recited invention. Claims 9, 16, 35, 36, 40, 49, 52, 94, 101, 165, and 238-240, as dependent from Claim 1, are indefinite for the same reason. For purposes of examination, it is assumed that Claim 1 is meant to recite “a polynucleotide having at least ... % sequence identity to SEQ ID NO: 77 and encoding a polypeptide having pectate lyase activity”.

Claims 9, 16, and 240 are indefinite because, in reciting activities not attributable to EC 4.2.2.2 (see NiceZyme enclosure), they are broader in scope than the claim from which they depend, Claim 1.

In Claim 16 the term “similar” is a relative term which renders the claim indefinite. The metes and bounds of the term “similar” are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Claim 240, as dependent from Claim 16, is indefinite for the same reason.

For Claim 24, line 17, it is unclear whether “the nucleic acid” refers to “An isolated, synthetic or recombinant nucleic acid” of line 1, or “a nucleic acid” of line 3. The skilled artisan

Art Unit: 1652

would not know the metes and bounds of the recited invention. For purposes of examination, it is assumed that “the nucleic acid” of line 17 refers to “a nucleic acid” of line 3.

Claim 27 is indefinite in the recitation of “hybridization” as this term is unclear absent a statement of the conditions under which the hybridization reaction is preformed. Nucleic acids that will hybridize under some hybridization conditions, will not necessarily hybridize under different conditions.

For each of Claim 31, line 3, Claim 35, line 1-2, Claim 36, line 2, Claim 40, line 1-2, Claim 49, line 2, Claim 52, line 2, and Claim 101, line 4, “a sequence” should be corrected to “the sequence”.

Claims 31 and 49 use the term “subsequence”, while other claims use the term “fragment”. It is unclear whether “subsequence” means fragment or something else, for example a three-dimensional structure made up of non-contiguous residues. The skilled artisan would not know the metes and bounds of the recited invention. For purposes of examination, it is assumed that “subsequence” means fragment.

Claim 49 is indefinite in the recitation of “hybridizing under stringent conditions” as this term is unclear absent a statement of the conditions under which the hybridization reaction is preformed. Nucleic acids that will hybridize under some hybridization conditions, will not necessarily hybridize under different conditions. The hybridization conditions described in paragraph [0026] are only exemplary and do not define the conditions recited in Claim 1.

For Claim 101, lines 5-6, “the polypeptide” should be corrected to “the encoded polypeptide”.

For Claim 101, line 6, “a recombinant polypeptide” should be corrected to “the recombinant polypeptide”.

For Claim 165, line 2, “a nucleic acid sequence” should be corrected to “the nucleic acid sequence”.

For Claim 165, line 3, “effected” should be corrected to “affected”.

For Claim 165, it is unclear whether “effected [affected] by use of a high activity promoter, a dicistronic vector or by gene amplification of the vector” are limitations for the recited method. The skilled artisan would not know the metes and bounds of the recited invention. For purposes of examination, it is assumed that said recitation does provide limitations for the recited method, i.e., a high activity promoter, a dicistronic vector or by gene amplification of the vector is used.

Claim Rejections - 35 USC § 112-First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Claims 1, 9, 16, 27, 31, 35, 36, 40, 49, 52, 94, 101, 165, and 238-240 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the nucleic acid molecule of SEQ ID NO: 77, as encoding the pectate lyase polypeptide of SEQ ID NO: 78, does not reasonably provide enablement for any variant of SEQ ID NO: 77. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In regards to this enablement rejection, the application disclosure and claims are compared per the factors indicated in the decision *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). These factors are considered when determining whether there is sufficient evidence to support a description that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. The factors include but are not limited to: (1) the nature of the invention; (2) the breath of the claims; (3) the predictability or unpredictability of the art; (4) the amount of direction or guidance presented; (5) the presence or absence of working examples; (6) the quantity of experimentation necessary; (7) the relative skill of those skilled in the art. Each factor is here addressed on the basis of a comparison of the disclosure, the claims, and the state of the prior art in the assessment of undue experimentation.

Claims 1, 9, 16, 27, 31, 49, 52 and 238-240 are so broad as to encompass any polynucleotide having at least 70% homology to SEQ ID NO: 77 or 131 (Claims 1, 9, 16, and 238-240), any nucleic acid molecule comprising at least 10 consecutive residues of a polynucleotide comprising SEQ ID NO: 77 or 131 (Claim 27), any primer pair capable of amplifying any polynucleotide having at least 70% homology to SEQ ID NO: 77 or 131 (Claim 31), any oligonucleotide capable of hybridizing under any conditions to any polynucleotide having at least 70% homology to SEQ ID NO: 77 or 131 (Claim 49), and any siRNA comprising any fragment of any polynucleotide having at least 70% homology to SEQ ID NO: 77 or 131 (Claim 52). The scope of each of these claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of nucleic acid molecules broadly encompassed by the claim. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in the

Art Unit: 1652

encoding polynucleotide's sequence and obtain the desired pectate lyase activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the protein's structure relates to its function.

However, in this case the disclosure is limited to the amino acid sequences of SEQ ID NO: 78 and 132 and the nucleotide sequences of SEQ ID NO: 77 and 131.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims. Furthermore, the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the results of such modifications are unpredictable (Galys et al, 1993; Whisstock et al, 2003). In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of Claims 1, 9, 16, 27, 31, 49, 52 and 238-240 which encompass any polynucleotide having at least 70% homology to SEQ ID NO: 77 (Claims 1, 9, 16, and 238-240), any nucleic acid molecule comprising at least 10 consecutive residues of a polynucleotide comprising SEQ ID NO: 77 or 131 (Claim 27), an primer pair capable of amplifying any polynucleotide having at least 70% homology to SEQ ID NO: 77 or 131 (Claim 31), any oligonucleotide capable of hybridizing under any conditions to any polynucleotide having at least 70% homology to SEQ ID NO: 77 or 131 (Claim 49), and any siRNA comprising any fragment of any polynucleotide having at least 70% homology to SEQ ID

Art Unit: 1652

NO: 77 or 131 (Claim 52). The specification does not support the broad scope of Claims 1, 9, 16, 27, 31, 49, 52 and 238-240 because the specification does not establish: (A) regions of the protein structure which may be modified without affecting the pectate lyase activity; (B) the general tolerance of the pectate lyase activity to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Since Claims 35, 36, 40, 94, 101, and 165 further recite vectors, host cells, nucleic acid arrays, and methods of expressing the nucleic acids of Claim 1, Claims 35, 36, 40, 94, 101, and 165 are also rejected under 35 U.S.C. 112 first paragraph due to lack of enablement for the same reasons discussed above.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of nucleic acid molecules with an enormous number of modifications of SEQ ID NO: 77. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of the identity of sequences having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Written Description

Claims 1, 9, 16, 27, 31, 35, 36, 40, 49, 52, 94, 101, 165, and 238-240 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

These claims are directed to a genus of nucleic acid molecules, wherein the genus comprises any polynucleotide having at least 70% homology to SEQ ID NO: 77 or 131 (Claims 1, 9, 16, and 238-240), any nucleic acid molecule comprising at least 10 consecutive residues of a polynucleotide comprising SEQ ID NO: 77 or 131 (Claim 27), an primer pair capable of amplifying any polynucleotide having at least 70% homology to SEQ ID NO: 77 or 131 (Claim 31), any oligonucleotide capable of hybridizing under any conditions to any polynucleotide having at least 70% homology to SEQ ID NO: 77 or 131 (Claim 49), and any siRNA comprising any fragment of any polynucleotide having at least 70% homology to SEQ ID NO: 77 or 131 (Claim 52). The specification teaches the structure of only two representative species of such nucleic acid molecules. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of encoding a pectate lyase. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Art Unit: 1652

Claims 35, 36, 40, 94, 101, and 165 as further reciting vectors, host cells, arrays, and methods of expressing the nucleic acids of Claim 1, are also rejected under 35 U.S.C. 112 first paragraph due to insufficient written description for the same reasons discussed above.

Claims 1, 9, 16, 35, 36, 40, 49, 52, 94, 101, 165, and 238-240 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the Inventors, at the time the application was filed, had possession of the claimed invention. Claim 1 introduces the limitations of a polynucleotide encoding a pectate lyase lacking a carbohydrate binding module and/or a pectin methyl esterase domain. The specification fails to describe said limitations and, thus, Claim 1, and dependent Claims 9, 16, 35, 36, 40, 49, 52, 94, 101, 165, and 238-240 are rejected under 35 U.S.C. 112, first paragraph, for introducing New Matter.

Claims 1, 9, 16, 35, 36, 40, 49, 52, 94, 101, 165, and 238-240 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the Inventors, at the time the application was filed, had possession of the claimed invention. Claim 1 introduces the limitations of polynucleotide variant of SEQ ID NO: 77 or 131 encoding a pectate lyase comprising a heterologous signal sequence, a heterologous carbohydrate binding module, a heterologous pectin methyl esterase domain, a heterologous catalytic domain, a heterologous prepro domain, a heterologous enzyme or a combination thereof. The specification fails to describe said

Art Unit: 1652

limitations and, thus, Claim 1, and dependent Claims 9, 16, 35, 36, 40, 49, 52, 94, 101, 165, and 238-240 are rejected under 35 U.S.C. 112, first paragraph, for introducing New Matter.

Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the Inventors, at the time the application was filed, had possession of the claimed invention. Claim 9 introduces the limitation of polynucleotide variant of SEQ ID NO: 77 or 131 encoding a pectate lyase having an activity to directly cleave galactan to galactose or galactooligomers. The specification fails to describe said limitation and, thus, Claim 1 is rejected under 35 U.S.C. 112, first paragraph, for introducing New Matter.

Claim 239 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the Inventors, at the time the application was filed, had possession of the claimed invention. Claim 239 introduces the limitation of polynucleotide variant of SEQ ID NO: 77 or 131 encoding a pectate lyase having thermostability. The specification fails to describe said limitation and, thus, Claim 239 is rejected under 35 U.S.C. 112, first paragraph, for introducing New Matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 9, 16, 24, 27, 31, 35, 36, 40, 49, 94, 101, 165, 238-240 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown et al, 2001 (IDS). Brown et al teach a polynucleotide encoding a polypeptide (Fig 2) having 72% identity with SEQ ID NO: 78 (see enclosed alignment). Said polynucleotide of Brown et al comprises a sequence that encodes a polypeptide having 84% identity to SEQ ID NO: 132 (see enclosed alignment). Brown et al further teach amplification primer pairs for their polynucleotide (pg 157, parag 2), an array comprising their polynucleotide (pg 158, parag 6), a method of making the encoded protein (pg 17, parag 8), and that their polypeptide is thermostable (pg 161, parag 1). Therefore, Claims 1, 9, 16, 24, 27, 31, 35, 36, 40, 49, 94, 101, 165, 238-240 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown et al, 2001.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al, 2001 in view of Carthew et al, 2001. The teachings of Brown et al are described above. Brown et al do not teach a double stranded inhibitory RNA comprising a subsequence of their polynucleotide. However, inhibitory RNA molecules were known in the art. For example, Carthew et al teach the use of double stranded inhibitory RNA for inhibiting gene expression. It would have been obvious to a person of ordinary skill in the art to use the method of Carthew et al to make a double stranded inhibitory RNA based on the polynucleotide of Brown et al.

Art Unit: 1652

Motivation to do so derives from the desire to use said double stranded inhibitory RNA to examine the importance of the pectate lyase of Brown et al, in *P. cellulosa*, the organism from which the polynucleotide was isolated. The expectation of success is high, as the making and using of double stranded inhibitory RNA was known in the art. Therefore, Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al, 2001 in view of Carthew et al, 2001.

Allowable Subject Matter

No claims are allowable

Final Comments

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943.

The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

Art Unit: 1652

applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SHERIDAN SWOPE/
Primary Examiner, Art Unit 1652